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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/734,836	12/12/2000	Tianci Luo	4-30922A/SYS	4435

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EXAMINER
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WINKLER, ULRIKE

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 09/06/2002

10

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/734,836

Applicant(s)

LUO ET AL.

Examiner

Ulrike Winkler, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☐ Claim(s) \_\_\_\_ is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-80 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____.  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other: _____.                                   |

***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-7, 23-25, 55-62, drawn to a bovine immunodeficiency virus vector (BIV) encoding *gag* and *pol*, classified in class 424, subclass 187.1.
- II. Claims 8-19, 40-54 drawn to a bovine immunodeficiency virus vector (BIV) encoding a transgene, classified in class 424, subclass 207.1.
- III. Claims 63-65, drawn to a viral surface protein expression construct, classified in class 424, subclass 224.1.
- IV. Claims 20-22, 26, 66-70, 74-76 drawn to a packaging cell and a method of making a packaging cell, classified in class 435, subclass 455.
- V. Claims 27-30, 71-73, 77, 80 drawn to a three-plasmid vector transfections method for producing virion particles, classified in class 435, subclass 465.
- VI. Claims 31, 32, 79 drawn to a method of transferring a gene of interest into a mammalian cell *in vitro* using a vector particle, classified in class 435, subclass 455.
- VII. Claims 31, 33, 79 drawn to a method of transferring a gene of interest into a mammalian cell *in vivo* using a vector particle, classified in class 80, subclass 23.
- VIII. Claims 34-36, drawn a two-plasmid vector transfections method for producing virion particles, classified in class 435, subclass 465.
- IX. Claims 37-39 drawn to a method of transferring a gene of interest into a mammalian cell using a vector particle, classified in class 435, subclass 455.

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- X. Claims 78 drawn to a method of transferring a gene to a mammalian cell by administering the a vector, classified in class 435, subclass 459.

For the invention of group I above, restriction to one of the following is also required under 35 USC 121. Therefore, if applicant elects the invention of group I, election is further required for one of inventions (A)-(G).

- |      |                               |   |                 |
|------|-------------------------------|---|-----------------|
| (A). | LTR                           | - | (claim 3)       |
| (B). | intron                        | - | (claims 25, 26) |
| (C). | transport element             | - | (claims 57-62)  |
| (D). | Tat + Rev                     | - | (claims 4,5)    |
| (E). | Rev                           | - | (claim 6)       |
| (F). | internal ribosomal entry site | - | (claim 24).     |
| (G). | 2 <sup>nd</sup> promoter      | - | (claim 7)       |

For each invention of groups II above, restriction to one of the following is also required under 35 USC 121. Therefore, if applicant elects one of the inventions of group II, election is further required for one of inventions (H)-(O).

- |      |  |   |                  |
|------|--|---|------------------|
| (H). | BIV packaging signal                     | - | (claim 9)        |
| (I). | 1 <sup>st</sup> promoter LTR             | - | (claims 10, 19)  |
| (J). | 1 <sup>st</sup> promoter CMV             | - | (claim 11)       |
| (K). | 2 <sup>nd</sup> promoter CMV, PKG or MND | - | (claim 12)       |
| (L). | gag or gag/pol                           | - | (claims 12, 14). |
| (M). | RRE                                      | - | (claims 15, 18)  |
| (N). | scaffold attachment region               | - | (claim 16)       |
| (O). | central polypurine tract                 | - | (claim 17)       |
| (P). | BIV DNA                                  | - | (claims 40-54)   |

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The inventions are distinct, each from the other because of the following reasons:

Inventions (A)-(G) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions, represent structurally different polypeptides and the polynucleotides encoding them. Therefore, where structural identity is required, such as for hybridization, expression or activity, the different sequences have different effects.

Inventions (H)-(P) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions, represent structurally different polypeptides and the polynucleotides encoding them. Therefore, where structural identity is required, such as for hybridization, expression or activity, the different sequences have different effects.

Claims 1, 2, 23, 55 link(s) inventions A-G. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 1, 2, 23, 55. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims

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of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Claims 8 link(s) inventions H-P. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 8. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Inventions I-III are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, inventions I-III have separate utility each plasmid produces different proteins which can be used as an immunogen. See MPEP § 806.05(d).

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Inventions V and I-III are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does necessarily rely solely on either subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because each plasmid encodes a different antigen. The subcombination has separate utility such as it expresses different proteins that have different antigenic properties.

Inventions I and III are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, inventions I and III have separate utility each plasmid produces different proteins which can be used as an immunogen. See MPEP § 806.05(d).

Inventions VIII and I, III are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does necessarily rely solely on either subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because each plasmid encodes a different antigen. The subcombination has separate utility such as it expresses different proteins that have different antigenic properties.

Groups VI, VII, IX and X are drawn to methods and each is distinct from the other because they utilize different starting materials, therefore the outcomes are not be expected to be

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the same. Group VI is drawn to a method for inserting a gene into a cell *in vitro*, the cell is not part a whole organism. Group VII is drawn to a method of inserting a gene into a cell *in vivo*, here a whole organism is treated with the viral particle. Group IX is drawn to a method of inserting a gene into a cell. The virion particles between groups VI, VII and IX are not made by the same methods indicating that the starting materials are not the same. Group IX is drawn to a method of transferring a gene into a mammalian cell by administering a plasmid vector. Though there may be overlap between these methods in question for groups VI, VII, IX and X, each utilizes different materials and therefore the outcome is expected to be different.

Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, and the literature and sequence searches required for each of the Groups are not required for another of the Groups, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).



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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 703-308-8294.

The examiner can normally be reached M-F, 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at 703-308-4027.

The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 or for informal communications use 703-308-4426.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Ulrike Winkler, Ph.D. 9/5/02